In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-855V

CRAIG FISHER,	*	Chief Special Master Corcoran
Petitioner,	*	Filed: December 4, 2023
v.	*	
SECRETARY OF HEALTH AND HUMAN SERVICES,	*	
Respondent.	*	

Andrew D. Downing, Downing, Allison & Jorgenson, for Petitioner.

Madelyn Weeks, U.S. Dep't of Justice, Washington, DC, for Respondent.

ENTITLEMENT DECISION[1]

On July 14, 2020, Craig Fisher filed a petition for compensation under the National Vaccine Injury Compensation Program (the "Vaccine Program").[2] Petition (ECF No. 1) ("Pet."). Petitioner alleges that he suffered from brachial neuritis[3] following an influenza ("flu") vaccine administered on January 19, 2018. Pet. at 1. A two-day Entitlement Hearing took place on April 13–14, 2023. Now, having reviewed the record and considered the expert testimony heard at trial, I deny entitlement, because the claimed injury has not been preponderantly established.

[1] Under Vaccine Rule 18(b), each party has fourteen (14) days within which to request redaction "of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy." Vaccine Rule 18(b). Otherwise, the whole Ruling will be available to the public in its present form. *Id.*

[2] The Vaccine Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3758, codified as amended at 42 U.S.C. §§ 300aa-10 through 34 (2012) [hereinafter "Vaccine Act" or "the Act"]. Individual section references hereafter will be to Section 300aa of the Act (but will omit the statutory prefix).

[3] As the experts who testified in this matter agreed, brachial neuritis can also be termed neuralgic amyotrophy or Parsonage-Turner Syndrome, interchangeably.

I. Factual Background

Prior to vaccination, Petitioner had a past medical history significant for obesity, diabetes mellitus with circulatory complication, acute abdominal pain syndrome, atrial fibrillation, coronary artery disease, chronic renal disease, hypertension, and sleep apnea. Ex. 3 at 13–14.

On January 12, 2018, Petitioner presented to St. Francis Hospital for epigastric pain. Ex. 3 at 4. Petitioner underwent an abdominal CT which showed "findings consistent with small bowel obstruction with [a] transition point in a left lower anterior abdominal wall hernia which demonstrate[d] fat stranding indicating incarceration." *Id.* at 13. The next day, Petitioner underwent a laparotomy with release of the small bowel obstruction and a ventral hernia repair. *Id.* at 15. Petitioner remained in the hospital until January 19, 2018, and was discharged with diagnoses including acute respiratory failure, hypokalemia, and ventral hernia repair. Ex. 3 at 82, 120; Ex. 2 at 7. Before being discharged, Petitioner received a flu vaccine in his left deltoid. Ex. 2 at 5.

Two days later, on January 21, 2018, Mr. Fisher was seen by a St. Francis home health care nurse for post-surgery aftercare. Ex. 7 at 10–73. At this time, he reported that he had not monitored his blood sugar levels, since they had improved after losing more than two hundred pounds. *Id.* at 34. He also stated that he was "planning to return to work in [the] near future." *Id.* at 34. However, Petitioner did not at this time report any left shoulder or arm pain. *Id.*

Onset of Arm Pain and Treatment

On January 23, 2018, Mr. Fisher saw his primary care physician ("PCP"), Patrick Murphy, M.D., at Warren Clinic South Memorial, with complaints of "severe [left] arm pain from [the] [f]lu vaccine [four] days ago," and noting that the "pain began [two] days after the injection." Ex. 9 at 235. Upon examination, Petitioner exhibited "tenderness [in his] left upper arm with no redness, warmth or firmness." *Id.* at 241. Dr. Murphy's assessment was left upper extremity pain and recommended Petitioner begin pain relief medication. *Id.*

The following day (January 24, 2018), Petitioner had a second home health care visit. Ex. 7 at 41. Mr. Fisher now reported left arm pain ranging 3/10—noting that within the last twenty-four hours, his pain had ranged from 0 to 6/10. *Id.* Petitioner described his pain as acute, intermittent, and exacerbated by movement. *Id.* Petitioner had another home health care visit on January 31, 2018, at which time he reiterated what he previously had reported. *Id.* at 60. And on February 7, 2018, Petitioner had yet another home health care visit, at which time he stated that "he [had] been released by the doctor to return back to work and want[ed] to be discharged, he [wa]s no longer home-bound and no longer ha[d] a skilled need." *Id.* at 73.

On March 30, 2018, Petitioner visited Dr. Murphy for treatment of his diabetes and hypertension. Ex. 9 at 246. A review of systems indicated left hand numbness and the assessment was diabetes mellitus with circulatory complication, including chronic diabetic polyneuropathy. *Id.* at 254–57.

Three months later, on July 3, 2018, Petitioner saw Dr. Murphy for management of his chronic conditions. Ex. 4 at 5–15. Petitioner's physical exam was normal, and Dr. Murphy's assessment included diabetic polyneuropathy. *Id.* at 12. Petitioner again saw Dr. Murphy on August 23, 2018, for urinary frequency and left arm pain. *Id.* at 20. At this visit, Petitioner reported that his onset of arm pain occurred in January 2018, due to an injection reaction. *Id.* Petitioner noted that the pain was in his "[l]eft upper arm to [his] fingers," and further described the pain as aching and moderate, with numbness in his second and third fingers. *Id.* A review of systems was positive for numbness, and Dr. Murphy's assessment included chronic polyneuropathy. *Id.*

Over the next ten months, Petitioner saw Dr. Murphy six times for ongoing management of his chronic conditions plus several other complaints, including bilateral ear pain and heartburn. Ex. 4 at 60, 70, 90, 106, 117, 126.

Subsequent Treatment

Petitioner saw neurologist Brooke McQueen, M.D., on September 24, 2019 (now more than a year and a half since the relevant vaccination), reporting "numbness, tingling, burning, and pins and needle sensation in the [left extremity] . . . [that] started about a year ago after the flu shot [in January 2018] . . .." Ex. 4 at 141. Petitioner noted numbness and tingling in his left hand, specifically in his second and third digits, and noted that his PCP thought the flu vaccination "hit a nerve" but that the pain would improve over time. *Id.* Dr. McQueen suspected that Petitioner might have carpal tunnel syndrome ("CTS") versus residual median sensory neuropathy from the flu vaccine. Dr. McQueen ordered electromyography ("EMG")[4] and nerve conduction study ("NCS")[5] tests—the results showing bilateral CTS and chronic cervical radiculopathy, with the left side worse than the right for both conditions. *Id.* at 160; Ex. 8 at 14–16, 20–25.

Six months later, on March 24, 2020, Petitioner had a telehealth appointment with Dr.

[4] "Electromyography" is defined as "an electrodiagnostic technique for recording the extracellular activity (action potentials and evoked potentials) of skeletal muscles at rest, during voluntary contractions, and during electrical stimulation; performed using any of a variety of surface electrodes, needle electrods, and devices for amplifying, transmitting, and recording the signals. *Electromyography*, https://www.dorlandsonline.com/dorland/definition?id=15854&searchterm=electromyography (last visited Dec. 4, 2023).

[5] "Nerve Conduction Study" is defined as "a diagnostic test that evaluates the function of [the] peripheral nerves. [It] can help detect the presence and extent of peripheral nerve damage." *Nerve Conduction Study*, https://my.clevelandclinic.org/health/treatments/24821-nerve-conduction-study (last visited Dec. 4, 2023).

McQueen, at which time he complained of continued "numbness/tingling in [his] left hand/fingers" and noted "some numbness, tingling, burning/sharp/electrical pain," in several of his left fingers Ex. 4 at 163. Upon examination, Petitioner exhibited normal range of motion with mild atrophy in the left thenar region. *Id.* at 174. Dr. McQueen's assessment included: "1) Neuropathy, 2) Cervical radiculopathy, 3) Bilateral carpel tunnel syndrome, 4) Neuropathic pain of hand, left." *Id.* at 175. Dr. McQueen also documented that Petitioner showed "mild pinched nerves in the neck; bilateral C5 and C7 on the left, nothing to do at this time, likely age related, may consider neck imaging in the future." *Id.* at 176. It was recommended that Petitioner wear wrist splints at night to help with his CTS. *Id.*

II. Witness Testimony

A. *Petitioner's Witnesses*

1. Craig Fisher

Petitioner was the only fact witness to testify. *See generally* Tr. at 8–57. He began his testimony addressing his pre-vaccination history, which he characterized as uneventful. Tr. at 9. Petitioner acknowledged that he had struggled with his weight, but that in the months leading up to his January 2018 vaccination, he had lost approximately one hundred pounds. *Id.* at 9–10.

Petitioner also briefly discussed his hospitalization prior to receipt of the flu vaccine on January 19, 2018. Tr. at 11–14. Around October-November 2017, he had been experiencing some intermittent stomach pain and underwent a H. Pylori[6] test—the result of which was positive. Tr. at 11. Petitioner's treating physician prescribed him some antibiotics to treat the H. Pylori. *Id.* Petitioner recalled getting ready to leave for an out-of-town convention when his stomach pain became a bigger concern. *Id.* at 12–13. His ex-wife advised him to go to the nearby emergency care clinic so that a CT scan could be performed to see if something more was going on—and after receiving such a scan, he was told that he needed to go to the hospital for further evaluation and care. *Id.* at 13. Once there, he was immediately prepped for surgery as it appeared he had a herniated intestine. *Id.* at 13. Petitioner remained in the hospital for a week following his surgery and was discharged on January 19, 2018. *Id.* at 14.

Petitioner recalled that before being discharged, he was advised to receive a flu vaccine, since contracting the flu after intestinal surgery could cause several complications. Tr. at 14. He had received the flu vaccine "pretty regularly" in the past, and while he had not planned to get one

[6] "Helicobacter Pylori" is defined as "a species that causes gastritis and peptic ulcers and is also associated with gastric cancer. Formerly called 'Campylobacter pylori.'" *Helicobacter Pylori*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=80297&searchterm=Helicobacter+pylori (last visited Dec. 4, 2023).

that year, he decided to do so in order to avoid any potential complications. *Id.* at 15. Two days after, on January 21, 2018, however, Petitioner woke up with an aching pain in his left upper arm so severe he worried he was having a heart attack. But an exam performed during a visit from his home health care team did not confirm this as the explanation for his pain. *Id.* at 16.

On January 23, 2018, Petitioner had a regularly-scheduled appointment with his PCP, Dr. Murphy—at which time he was seeking additional treatment options for his pain, as it had gotten to the point where it was keeping him awake at night. Tr. at 20–21. Petitioner further noted that he had not taken any pain medication since his hernia surgery (out of concerns for avoiding dependency on it), but that "[the pain] was more than [he] could bear," and that he was "desperately looking for a solution." *Id.* at 21–22.

Then, on or about January 30, 2018, Petitioner began experiencing a numbness/tingling sensation in his index finger which eventually spread to his middle finger, thumb, and half of his left hand. Tr. at 27. He further testified that the pain in his shoulder "was horrible," and that "the only relief [he] found was icing it down" or scheduling massage appointments. *Id.* Over the course of the next seven to eight months, Petitioner reported to Dr. Murphy on several different occasions, since his symptoms persisted—and remain to this day. *Id.* at 32–33. He eventually sought a neurology referral from Dr. Murphy at an August 2018 appointment but noted that he was unable to schedule a consult until approximately a year later, on September 24, 2019. *Id.* at 34.

Petitioner concluded his testimony by briefly emphasizing that the injury had negatively impacted his ability to work—noting that he eventually had to transition to a half-time position approximately six months following vaccination. Tr. at 37. Although he was hoping to return to a full-time position, it was "difficult to focus" due to the lack of sleep from the pain. *Id.*

2. Peter-Brian Andersson, M.D.

Dr. Andersson, a clinical neurologist, prepared two written reports for Petitioner and testified in support of the contention that Petitioner suffered brachial neuritis caused by his receipt of the flu vaccine. *See generally* Tr. at 59–179; Report, dated Feb. 18, 2022, filed as Ex. 10 (ECF No. 26-1) ("Andersson First Rep."); Report, dated Dec. 18, 2022, filed as Ex. 42 (ECF NO. 41-1) ("Andersson Second Rep.").

Dr. Andersson received his medical degree from the University of Cape Town, South Africa, in 1986, as well as an honors degree in Medical Biochemistry in 1988. Tr. at 59–60; Curriculum Vitae, filed as Ex. 11 (ECF NO. 26-2) ("Andersson CV") at 1. Thereafter, Dr. Andersson received a Ph.D. equivalent in experimental pathology from the University of Oxford, United Kingdom in 1991. Tr. at 61; Andersson CV at 1. He later became a college lecturer in Immunology at Christ Church, University of Oxford. *Id.* Dr. Andersson then completed his

residency in neurology, followed by a fellowship in Neuroimmunology and Multiple Sclerosis at the University of California, San Francisco. Tr. at 62; Andersson CV at 1. In addition to completing the previously mentioned fellowship, Dr. Andersson also completed a Neuromuscular fellowship at Oregon Health Sciences University as well as at Stanford University. *Id.* He is licensed to practice medicine in California, and he is board certified by the American Board of Psychiatry and Neurology and the American Board of Electrodiagnostic Medicine. Tr. at 62–63; Andersson CV at 1. He has published several articles on the topic of neurology and immune-mediated diseases, and has treated over a hundred cases of brachial neuritis, as well as thousands of cases for cervical radiculopathy, ulnar neuropathy, and carpal tunnel syndrome. Tr. at 64; Andersson CV at 2.

Dr. Andersson began his testimony with a brief overview of Petitioner's pre-vaccination history—emphasizing that upon his admission to the hospital on January 12, 2018, he had not been experiencing any numbness, arthralgias, or myalgias (making his post-vaccination condition meaningful by contrast). Tr. at 70; Ex. 3 at 114–15. Dr. Andersson then provided an explanation of brachial neuritis and its associated symptoms. Tr. at 71. Brachial neuritis is an inflammatory condition with "an acute onset that affects the brachial plexus and related nerves and at times roots." *Id.* at 71–72. He identified several distinctive factors associated with brachial neuritis: striking severity; striking distribution; striking persistence; apparent lack of cause; and associated neurogenic features—all of which were observed in Petitioner, according to Dr. Andersson. Tr. at 72–73; Andersson First Rep. at 7–8.

Dr. Andersson analyzed each factor relevant to the diagnosis, maintaining that Petitioner's brachial neuritis was more likely a vaccine-induced sensory form of brachial neuritis rather than cervical radiculopathy or CTS. Tr. at 137–38; Andersson First Rep. at 7–8. Dr. Andersson emphasized Petitioner's reported widespread distribution of severe pain, sudden onset, and intractability as distinctive of brachial neuritis—further noting Petitioner's initial concern that he was suffering a heart attack, his inability to sleep, and the ineffectiveness of pain medication. Tr. at 134; Andersson First Rep. at 7–8.

Dr. Andersson next explained that brachial neuritis is typically a "patchy syndrome," but that Petitioner exhibited "very widespread, yet very severe [pain], and brachial neuritis does that." Tr. at 135. Moreover, Petitioner's pain not only began without any apparent cause, but it never seemed to improve. *Id.* at 135–36. Dr. Andersson further commented on the persistence of Petitioner's pain—noting that "other structures that have a differential for casing pain, when they [are] musculoskeletal, they generally exacerbate or relive, depending on your position or movement," but Petitioner did not experience later reduction in symptoms. *Id.* at 137–38. Accordingly, Dr. Andersson opined, brachial neuritis was the only diagnosis that would unify all of Petitioner's presenting symptoms. *Id.*

Brachial neuritis can be triggered by an activation of the immune system—including, but

not limited to, infection, vaccination, or recovery from surgery. Tr. at 75, 78–79; Anderson First Rep. at 10; J. LJspeert et al., *Neuralgic Amyotrophy*, 34 Current Opinion Neurology 605, 608 (2021), filed as Ex. 15 (ECF No. 27-4) ("LJspeert") (finding that "any immune-related factor can trigger NA, including infection, vaccination, immunotherapy such as interferon or immune-checkpoint inhibitors, recovery from surgery, pregnancy or childbirth, trauma or psychological distress"); G. Suarez et al., *Immune Brachial Plexus Neuropathy: Suggestive Evidence for an Inflammatory-Immune Pathogenesis*, 46 Neurology 559, 560 (1996), filed as Ex. 19 (ECF No. 27-8). However, Dr. Andersson hesitated to endorse the opinion that surgery can be a mechanism of injury for brachial neuritis—arguing that the literature is simply unclear as to the degree of association. Tr. at 77–78.

To explain the mechanistic immune process that would result in brachial neuritis, Dr. Andersson provided testimony regarding the distinctions between a primary and secondary immune response. The primary immune response occurs in "a naïve host who [is] generating an immune response for the first time," whereas "in the secondary, there is a memory" or a "recall of that original immune response in the T and the B cells [] [and] plasma cells." Tr. at 80. An individual's secondary immune response would become more rapid as well as more vigorous when an individual encountered antigens again, in subsequent exposures—and as Dr. Andersson explained, this is not only exactly what vaccination is predicated on, but likely explains the nature of Petitioner's immune response to the flu vaccine he received. *Id.* at 81; Andersson First Rep. at 11–12.

In support of his opinion that Petitioner's brachial neuritis was likely mediated by a secondary/adaptive immune process, Dr. Andersson offered several items of literature. Tr. at 83; Andersson First Rep. at 11–12; *See, e.g.*, F. Vriesendorp et al., *Anti-Peripheral Nerve Myelin Antibodies and Terminal Activation Products of Complement in Serum of Patients with Acute Brachial Plexus Neuropathy*, 50 Arch. Neurology 1301, 1303 (1993), filed as Ex. 23 (ECF No. 28-2) ("Vriesendrop") (supporting the notion that complement-dependent, antibody-mediated demyelination may participate in the initial peripheral nerve damage or augment an ongoing process based on the detection of anti-PNM antibodies and complement activation products in three patients with brachial plexus neuropathy). Some items were case reports. A. Hamati-Haddad & F. Fenichel, *Brachial Neuritis following Routine Childhood Immunization for Diphtheria, Tetanus, and Pertussis (DTP): Report of Two Cases and Review of the Literature*, 99 Pediatrics 602 (1997), filed as Ex. 32 (ECF No. 29-1) (reporting two cases of brachial neuritis following receipt of the tetanus toxoid vaccination in adults); S. Queler et al., *Parsonage-Turner Syndrome following COVID-19 Vaccination: MR Neurography*, 302 Radiology 84, 85 (2022), filed as Ex. 33 (ECF No. 29-2) ("Queler") (reporting onset of Parsonage-Turner syndrome post-vaccination within 28 days and as early as the same day as immunization).

Dr. Andersson also opined that the timeframe in which Petitioner's brachial neuritis began

was consistent with an adaptive/secondary immune-mediated process. He noted that when an individual is exposed to viral antigenic material to which he or she has previously been exposed, an immune-mediated process can occur more rapidly. Tr. at 93. As Dr. Andersson explained, an individual will "have a host who has an immune system primed and ready to go, . . . and now they have an antigenic trigger from a vaccination that will generate a response to this vaccine." *Id.* In so responding, the immune system has also "activated clones of cells that were memory cells, [] so the effect is now to generate a host attack . . . and this attack is going to be severe [and rapid] because the immune response is secondary." *Id.* P. Tsairis et al., *Natural History of Brachial Plexus Neuropathy*, 27 Arch Neurology 109, 111 (1972), filed as Ex. 16 (ECF No. 27-5) ("Tsairis") (finding that "the most striking feature of this disease was the rapid onset of pain usually followed by muscle weakness or paralysis"). Thus, he deemed an onset of two to three days post-vaccination to be medically acceptable.

B. *Respondent's Witnesses*

1. Brian Callaghan, M.D.

Dr. Callaghan, a neuromuscular specialist in treatment of neuropathies like brachial neuritis, prepared two written reports for Respondent and testified for Respondent in support of the contention that there is not a causal association between the flu vaccine and brachial neuritis. *See generally* Tr. at 181–281; Report, dated June 2, 2022, filed as Ex. A (ECF No. 31-1) ("Callaghan First Rep."); Report, dated Feb. 19, 2023, filed as Ex. E (ECF No. 44-1) ("Callaghan Second Rep.").

Dr. Callaghan received his undergraduate degree from the University of Michigan in 1999, his medical degree from the University of Pennsylvania in 2004, and his Masters in Science from the University of Michigan in 2011. Curriculum Vitae, filed as Ex. B (ECF No. 31-2) ("Callaghan CV") at 1; Tr. at 183–84. He became a clinical lecturer at the University of Michigan Health System's Department of Neurology in 2009 and has been an Associate Professor of Neurology there since 2018. Callaghan CV at 1; Tr. at 182. He is licensed to practice medicine in Michigan, and he is board certified by the American Board of Psychiatry and Neurology and the American Board of Electrodiagnostic Medicine. *Id.* Dr. Callaghan has published mover than 120 articles and medical book chapters, with a majority focusing on neuropathy, and including the appropriate diagnostic evaluation and treatment of neuropathy. Callaghan CV at 14–24; Callaghan First Rep. at 1; Tr. at 186. Dr. Callaghan has averred that he has treated more than 50 patients with brachial neuritis. Callaghan Rep. at 1.

Dr. Callaghan began his testimony addressing the rarity of both brachial neuritis and pure sensory brachial neuritis—noting that in his fifteen years as a neurologist, he has treated only a handful of cases for brachial neuritis, but has never seen a case of pure sensory brachial neuritis.

Tr. at 189. He defined brachial neuritis to be "a syndrome characterized by pain, followed by weakness and atrophy, that usually occurs in one limb and evolves over a series of months." *Id.* He then briefly addressed the diagnostic criteria for brachial neuritis—emphasizing that "in the absence of neurographic studies, [diagnosis] requires weakness in [the] muscles supplied by more than one peripheral nerve, and then EMG and nerve conduction studies need to localize injury to the brachial plexus." *Id.* at 191; Callaghan First Rep. at 4–5. This kind of testing was in fact critical to the diagnosis. Tr. at 206.

Dr. Callaghan testified that he agreed with Petitioner's treating physicians: Petitioner neither suffered from brachial neuritis nor from a pure sensory form of the condition, but instead more likely suffered from diabetic neuropathy, cervical radiculopathy, and/or CTS. *Id.* at 194. Indeed, there was no mention, even as part of a differential diagnosis, of brachial neuritis in treater records, and he was never formally so diagnosed. *Id.* at 195. Rather, Petitioner's diagnosis was consistent with the symptoms he had reported to his treating physicians, and Dr. Callaghan emphasized that the nature of those symptoms, as well as the pain involved, were common to diabetic neuropathy, cervical radiculopathy, or CTS.[7] *Id.* at 197–98. He would have made the same diagnoses as Petitioner's treating physicians did, and would not have considered a pure sensory form of brachial neuritis as explanatory, given the record. *Id.* at 209.

Dr. Callaghan went on to identify why Petitioner's reported symptoms plus exam and testing findings did not satisfy the diagnostic criteria for brachial neuritis. Tr. at 215; Callaghan First Rep. at 5. For example, Petitioner never reported weakness in the affected arm, nor was it demonstrated on exam—thus not meeting criterion two. *Id.* Additionally, Petitioner did not display motor, sensory, and reflex deficiencies upon examination. The degree of pain Petitioner was reporting was not a factor favoring a brachial neuritis diagnosis, since actual severity of these conditions often did not correlate with complained-of pain levels. *Id.* Moreover, Petitioner's symptoms did not appear to be widespread, but instead were isolated to his left upper extremity and three left hand fingers. *Id*. at 221–22. According to Dr. Callaghan, patients suffering from brachial plexus injuries typically experience more widespread symptoms. *Id.*

The EMG/NCS testing performed in this case was also not confirmatory for a brachial neuritis diagnosis, in Dr. Callaghan's view. The relevant testing revealed "things that are super common and completely describe the patient's symptoms, and so cervical radiculopathy at those levels and a carpal tunnel syndrome would be exactly expected to give the symptoms that [Petitioner] presented with." Tr. at 206, 216. The results did not confirm the existence of the kind of dysfunction that could be attributed to the brachial plexus. Callaghan First Rep. at 5. Petitioner's EMG/NCS results were also consistent with some bilateral injuries, specifically on the left side, as well as cervical radiculopathy at C5 and C7 spine levels. *Id.* at 206–07.

[7] Dr. Callaghan defined CTS as "a mechanical injury of the median nerve in the carpal tunnel itself," deeming it not only the most common neuropathy, but particularly prevalent for patients with diabetes. Tr. at 200.

Petitioner's past medical history, Dr. Callaghan opined, suggested a credible alternative explanation for Petitioner's symptoms. That history was significant for diabetes, making Petitioner more prone to "*every* peripheral nerve manifestation." Tr. at 196 (emphasis added). Diabetes, Dr. Callaghan explained, can often cause a form of polyneuropathy or increase an individual's risk of radiculopathy, and can even lead to an increased chance of developing mononeuropathies, including carpal tunnel syndrome. *Id.* There was even other evidence consistent with the conclusion that such processes were already under way. Petitioner suffered from C5/C7 radiculopathy, which Dr. Callaghan described as an "injury to the nerve roots in the neck"—noting that C5 typically causes pain that travels down the arm, and oftentimes involves the shoulder and the first few digits whereas C7 usually involves the middle finger. *Id.* at 196–97. Petitioner's diagnosis was consistent with the symptoms Petitioner reported to his treating physicians—and in fact, in Dr. Callaghan's opinion the pain Petitioner described could equally implicate the existence of a diabetic neuropathy, cervical radiculopathy, or CTS. *Id.* at 197–98.

Dr. Callaghan then briefly discussed several post-vaccination visits with Petitioner's treating physicians—but focused specifically on his visits with Dr. McQueen in 2019-20. Tr. at 203. By this time (18-plus months post-vaccination), Petitioner was describing pain in the left upper arm that traveled down into his fingers and hand accompanied by numbness in his second and third fingers. But in Dr. Callaghan's view, such symptoms were fully consistent with Petitioner's prior diagnosis of C5/C7 radiculopathy and carpal tunnel syndrome. *Id.*

In addition to disputing the propriety of a brachial neuritis diagnosis, Dr. Callaghan denied that the flu vaccine could likely cause the condition. Callaghan First Rep. at 5–6. In so doing, he addressed Dr. Andersson's effort to analogize the autoimmune process deemed to be possibly triggered by the flu vaccine, resulting in GBS. In Dr. Callaghan's view, GBS and brachial neuritis were wholly-distinct illnesses (even if both are peripheral nerve injuries), since GBS affects "the myelin or covering of the nerve," whereas brachial neuritis is "an injury to the blood vessels that *supply* the nerve." Tr. at 222 (emphasis added). They otherwise have different underlying pathologies, require different forms of treatment, and result in separate kinds of impacts to the body. *Id.* As a result, Dr. Callaghan deemed Dr. Andersson's assertion that brachial neuritis essentially operates the same way as GBS to amount to a be "huge leap of faith." *Id.* at 223. Dr. Callaghan further maintained that he could find no reliable literature support establishing a likely causal link between the flu vaccine and brachial neuritis. *Id.* at 223–24.

2. Andrew MacGinnitie, M.D.

Dr. MacGinnitie, an allergist/immunologist, prepared two written reports for Respondent and testified for Respondent, opining that there is no causal connection between the flu vaccine and the neurologic problems Petitioner suffered (however they are defined). *See generally* Tr. at 280–342; Report, dated May 31, 2022, filed as Ex. C (ECF No. 31-3) ("MacGinnitie First Rep."); Report, dated Feb. 15, 2023, filed as Ex. F (ECF No. 44-2) ("MacGinnitie Second Rep.").

Dr. MacGinnitie received his bachelor's degree from Yale University and then attended the University of Chicago, Pritzker School of Medicine, where he received both an M.D. and a Ph.D. from the Department of Pathology. Curriculum Vitae, filed as Ex. D (ECF No. 31-4) ("MacGinnitie CV") at 1; Tr. at 281–82. Thereafter, he completed a residency in pediatrics in the Boston Combined Residency Program, a joint venture of Boston Children's Hospital and Boston Medica Center, followed by an Allergy/Immunology fellowship at Boston Children's Hospital. *Id.*; MacGinnitie First Rep. at 1–2. Dr. MacGinnitie is an Associate Professor Pediatrics at Harvard Medical School, as well as the Clinical Chief for the Division of Immunology at Boston Children's Hospital where he directs clinical operations for Allergy/Immunology, Rheumatology and Dermatology. MacGinnitie CV at 1–2; MacGinnitie First Rep. at 1; Tr. at 283–84. He is board certified in both Pediatrics and Allery and Clinical Immunology. MacGinnitie CV at 11; Tr. at 281. Dr. MacGinnitie has averred that he treats approximately 1,700 patients annually, and has extensive experience in caring for both children and adults with a variety of immunologic diseases, such as reactions to vaccines. MacGinnitie First Rep. at 2.

Dr. MacGinnitie began his testimony by noting that he would not be offering an opinion on the diagnosis of brachial neuritis, deferring on that issue to Dr. Callaghan. Tr. at 286–87. Instead, Dr. MacGinnitie provided his view as to whether there likely exists a reasonable mechanism by which the flu vaccine could trigger brachial neuritis (and finding that there was not). *Id.* at 287.

In so opining, Dr. MacGinnitie provided an explanation for the concept of molecular mimicry (which Dr. Andersson's theory appeared to rely upon). Tr. at 287–89. He explained that the immune system has two responsive "arms": the innate response, which immediately responds to antigenic exposure, sometimes involving or promoting inflammation, and then the second, adaptive response—i.e., the targeting of specific epitopes, typically proteins, on infections such as bacteria or viruses. Tr. at 288. Dr. MacGinnitie allowed that Petitioner's receipt of the flu vaccine would implicate the secondary, adaptive response, since the immune system would likely recognize the flu antigens from prior vaccine exposures (despite differences in the vaccine from year to year). Tr. at 302–03.

Dr. MacGinnitie agreed with Dr. Andersson's explanation of molecular mimicry as involving the secondary/adaptive response, and occurring where "there's some immune stimulus, typically thought of to be an infection—but could be vaccination or environmental exposure—and there is an antigen or epitope [that is] recognized by [the] immune system [and] is similar in structure to a human protein," later resulting in the production of antibodies that recognize, and attack, both the foreign antigen as well as the similar human protein. Tr. at 287–88. In Dr. MacGinnitie's experience, four criteria must be demonstrated[8] if molecular mimicry is to be

[8] I note that the criteria Dr. MacGinnitie discusses do not constitute elements of the legal test Petitioner must satisfy to meet his burden of proof. But they *do* stand as the kinds of factors that the scientific community would consider significant in whether molecular mimicry deserves explanatory weight, and I therefore evaluate them only in that

credibly invoked as an explanatory mechanism for a disease process. L. Peterson & R. Fujinami, *Molecular Mimicry*, 13 (Yehuda Shoenfeld et al. eds., 2nd ed. 2007) ("Peterson and Fujinami"). These are the "similarity between a host epitope and an epitope of a microorganism or environmental agent; detection of antibodies or T cells cross-reactive with both epitopes in patients with the autoimmune disease; epidemiological link between exposure to the environmental agent or microbe and development of autoimmune disease; and reproducibility of autoimmunity in an animal model following sensitization with the epitopes, infection with the microbe or exposure to the environmental agent." Tr. at 290; MacGinnitie Second Rep. at 1. Peterson Fujinami at 13.

In this case, molecular mimicry could not be demonstrated to be a reliable explanation for how the flu vaccine could cause brachial neuritis. In particular, Dr. MacGinnitie noted, the first and second criteria for deeming molecular mimicry an apt explanation for an immune-mediated process were absent. Tr. at 16. Thus, Dr. Andersson had failed to identify any homology between flu vaccine antigenic amino acid sequences and the human nerve proteins which would presumably be targeted. *Id.* at 288–89. Without establishing a specific basis for an errant cross-attack through the identification of some homology one could essentially maintain that "really anything that stimulates [an individual's] immune system could cause any autoimmune disease"—which he maintained is not a very robust and convincing application. *Id.* at 295. Moreover, Dr. Andersson had not specified whether the immune response elicited B cells or T cells in carrying out its disease-causing process. *Id.* at 289, 292. And no cross-reactive antibodies or T cells that might theoretically drive an autoimmune process had been identified. Dr. MacGinnitie also felt it significant that little medical literature supported a causal relationship between the flu vaccine and brachial neuritis. Tr. at 296. He noted that, in conducting his own research for purposes of this hearing, he had found nothing so supportive except for a "handful of case reports [for] influenza and other vaccines but no epidemiologic studies that show a connection." *Id.*

There was otherwise, Dr. MacGinnitie maintained, no reason to deem the vaccine Petitioner received as more likely causal than several other potential explanations for Petitioner's symptoms evident from the medical record. He noted, for example, that "some infections could trigger inflammation in an organ leading to autoimmunity without any evidence of molecular mimicry." Tr. at 309. Although there are "significant safeguards in the immune system to protect against autoimmunity," such mechanisms can be breached either through genetic mutations or other mechanisms. Tr. at 309. Surgery is another common preceding event for brachial neuritis, "roughly on the order of magnitude [as] vaccination." *Id.* at 310. Here, eight to nine days prior to development of symptoms argued to reflect brachial neuritis, Petitioner had undergone surgery to repair an incarcerated hernia—which "would make that a much more plausible trigger of brachial neuritis than vaccination." *Id.* In fact, Dr. MacGinnitie stressed, surgery is a "significant immune stimulus"—noting that damage-associated molecular patterns are released by damaged cells, and

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regard (since they provide some insight into why an expert might not deem molecular mimicry to stand as a persuasive explanation for an immune-mediated injury).

that when an individual undergoes any type of surgery or experiences trauma, "patients have a significant inflammatory response." *Id.* at 311.

Dr. MacGinnitie also opined that Petitioner's onset date was inconsistent with Dr. Andersson's proposed theory, and its reliance on molecular mimicry. An onset of 40 hours post-vaccination "is too fast for an adaptive immune response, which would be required for molecular mimicry." Tr. at 289–90. This was true in his view even though he agreed that Petitioner (having been exposed to prior versions of the flu vaccine) would likely have a shorter adaptive response. *Id.* at 302–03. The adaptive response would take three days or more to manifest antibodies capable of the kind of cross-reaction implicated by molecular mimicry. Tr. at 298.

III. Post-Hearing Reports

After the hearing, I informed the parties that although it appeared Petitioner primarily relied on a theory involving an adaptive immune response as mediating the alleged brachial neuritis, it seemed as if Dr. Andersson had allowed for an innate response as *also* potentially driving brachial neuritis (and that this might be more consistent with the fast, post-vaccination onset of Petitioner's symptoms). Thus, the parties were afforded a final opportunity to submit a single supplemental report addressing whether brachial neuritis can be caused by an innate immune response. Both sides offered a report from one expert. *See* Dr. Andersson Report, dated June 15, 2023, (ECF No. 67-1) ("Andersson Supp. Rep."); Dr. MacGinnitie Report, dated June 13, 2023 (ECF No 66-1) ("MacGinnitie Supp. Rep.").

Dr. Andersson's Post-Hearing Report

Dr. Andersson first acknowledged that although he had referred to the innate immune response as pathogenic at hearing, he did not use that specific term in his reports. He nevertheless emphasized that "brachial neuritis is an immune mediated condition and as such it has two potential pathogenic mechanisms by which it is affected"—the adaptive *and* innate responses. Andersson Supp. Rep. at 1. In this report, Dr. Andersson addressed each system and discussed their respective relevance to Petitioner's alleged injury and claim. *Id.*

As Dr. Andersson noted, "[t]he pathophysiology of NA remains uncertain, although it often suggests an auto-immune origin such as in Guillain-Barré syndrome." Andersson Supp. Rep. at 1; P. Seror, *Neuralgic Amyotrophy: An Update*, 84 Joint Bone Spine 153, 156 (2017), filed as Ex. 43 (ECF No. 38-1). He further noted that even if the timing of onset from vaccination to injury in this case (two days) was relatively rapid for an adaptive immune response, such timing did not rule out an adaptive-mediated path. Andersson Supp. Rep. at 1. Indeed, because Petitioner had previously been exposed to the flu vaccine, an immune memory-oriented response had likely occurred, and it would happen in a shorter timeframe. *Id.*

However, Dr. Andersson also opined that brachial neuritis could be the result of an aberrant *innate* immune response. The innate response "is the body's first line of defense against pathogens

entering the body and it responds in the same way to all foreign substances." Andersson Supp. Rep. at 2. Studies discussing histopathologic evidence relevant to brachial neuritis had observed "[i]ncreased levels of complement[9] C5-C9 and decreased levels of C3," as well the "presence of "local inflammatory infiltrates, severe pain caused by the release of inflammatory mediators and ischemia of the nervi nervorum, and acute damage to the paranodal regions of large nerve fibers.'" *Id.*; J. Van Eijk et al., *Neuralgic Amyotrophy: An Update on Diagnosis, Pathophysiology, and Treatment*, 53 Muscle & Nerve 337, 340 (2016), filed as Ex. 18 (ECF No. 27-7); LJspeert at 4. Additionally, Dr. Andersson relied on statements made in the LJspeert article, which argued that essentially any factor that provokes the innate immune response can constitute an immunological trigger. Andersson Second Supp. Rep. at 2; LJspeert at 4.

In fact, it might be difficult to differentiate the contributions of the innate versus adaptive immune response in attempting to identify the primary impetus for brachial neuritis. As Dr. Andersson noted, "the histopathology of brachial plexitis as inflammatory and the deposition of complement that is the [contribution of the] innate immune system" meant that the innate arm was likely also important to the disease process. Andersson Supp. Rep. at 2; Andersson Second Rep. at 11. The evidence of complement activation in brachial neuritis was "further evidence that an acute onset of symptoms within just a couple of days following a trigger is due to an innate immune-mediated response." *Id.* Dr. Andersson thus maintained that an innate immune response could lead to the development of brachial neuritis through an "acute, nonspecific, immune-mediated inflammatory response triggered by localized inflammation, complement cascade, and localized lymphocytic infiltration"—all present in Petitioner's case. *Id.* at 3.

Dr. Andersson concluded his final report with a comment on whether Petitioner's pre-vaccination hernia surgery could explain his injury. Although he could not dispute the fact of the surgery, Dr. Andersson maintained that there was a lack of an explanatory mechanism by which the surgery could have caused his brachial neuritis, adding that an interval of eight days post-surgery (January 13-21) would exclude the possibility that immune stimulation due to surgery was explanatory.

Dr. MacGinnitie's Post-Hearing Report

Dr. MacGinnitie began his supplemental report with a brief overview of the nature of the innate and adaptive immune responses—noting that "innate immunity involves defense mechanisms that are not specific for any single pathogen, while the adaptive immune response can generate a near infinite number of receptors, capable of recognizing almost any protein or other molecules." MacGinnitie Supp. Rep. at 2–6. Although the two arms of the immune response might work together to cause brachial neuritis, the adaptive arm better "explained" the disease's

[9] "Complement" is defined as "the entire functionally related system comprising at least 20 distinct serum proteins, their cellular receptors, and related regulatory proteins that is the effector not only of immune cytolysis but also of other biologic functions including anaphylaxis, phagocytosis, opsonization, and hemolysis." *Complement*, Dorland's Medical Dictionary Online, https://www.dorlandsonline.com/dorland/definition?id=10705&searchterm=complement (last visited on Dec. 4, 2023).

pathogenic process, even if the innate arm also played a role. *Id.* at 6.[10] Indeed, although complement is released via the innate immune response, the articles Dr. Andersson relied on also discussed the presence of *both* anti-myelin antibodies and complement activation—suggesting that an innate response might only occur *after* the adaptive immune response produces autoantibodies that instigate the disease initially. *Id.*; Vriesendrop at 1303. Other, more recent literature also illustrated the coordinated role the innate and adaptive immune responses play in the development of autoimmune diseases. MacGinnitie Supp. Rep. at 9; G. Wigerbald et al., *Neutrophil Extracellular Traps in Systemic Autoimmune and Autoinflammatory Diseases*, 23 Nat. Rev. Immunology 274 (2023).[11]

Dr. MacGinnitie therefore denied that an innate immune response alone could cause brachial neuritis. MacGinnitie Supp. Rep. at 10. Because the innate response is *not* antigen-specific, it is unlikely that "generalized inflammation could trigger the organ-specific autoimmunity seen in [brachial neuritis] (or pure sensory BN)." *Id.* Dr. MacGinnitie acknowledged one case report cited by Dr. Andersson involving a patient who developed symptoms of brachial neuritis within approximately 13 hours after receiving the Covid-19 vaccine, but emphasized the limitations of relying on such case reports. *Id.*; Queler at 1. In addition, the flu vaccine is generally not a strong stimulus for the innate immune response, especially since "the majority of influenza vaccines administered in the US are unadjuvanted, including the one [Petitioner] received, where adjuvants are materials added to vaccines specifically to trigger the innate immune system." MacGinnitie Supp. Rep. at 11.

An innate response also could not explain a purely sensory form of brachial neuritis. MacGinnitie Supp. Rep. at 11. In almost all of the literature discussing an immune mediated pathology for brachial neuritis, the adaptive immune response was discussed. *Id.* Moreover, innate immunity is *not* antigen-specific, and thus "innate immune activation would not explain symptoms limited to the peripheral nervous system." *Id.* He concluded by reiterating his prior point that the timeframe for Petitioner's onset was too rapid to be attributed to an adaptive response. *Id.*

IV. Procedural History

As noted above, this claim was initiated in July 2020, and the matter was originally designated as a "Special Processing Unit" (the "SPU") case, based on anticipation that the claim was likely to settle. ECF Nos. 1, 4. All medical records with and an amended Statement of Completion were filed by December 2020. ECF No. 14. Respondent filed his Rule 4(c) Report contesting Petitioner's right to compensation on June 16, 2021. ECF No. 21, and the matter was subsequently transferred out of SPU to my regular docket. Thereafter, expert reports were filed,

[10] Dr. MacGinnitie disagreed with Dr. Andersson's contention, however, that macrophages are only involved in the innate immune response. As a result, Dr. Andersson's point about histopathology findings relating to brachial neuritis was supportive of both arms playing a role. MacGinnitie Supp. Rep. at 6.

[11] I note, however, that Respondent did not file this item of literature.

and a two-day entitlement hearing was held on April 13-14, 2023. The parties have filed their supplemental expert reports addressing whether brachial neuritis can be caused by an innate immune response, and the matter is now ripe for resolution.

V. Applicable Legal Standards

A. *Petitioner's Overall Burden in Vaccine Program Cases*

To receive compensation in the Vaccine Program, a petitioner must prove either: (1) that he suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations in question within a statutorily prescribed period of time or, in the alternative, (2) that his illnesses were actually caused by a vaccine (a "Non-Table Injury"). *See* Sections 13(a)(1)(A), 11(c)(1), and 14(a), as amended by 42 C.F.R. § 100.3; § 11(c)(1)(C)(ii)(I); *see also Moberly v. Sec'y of Health & Hum. Servs.*, 592 F.3d 1315, 1321 (Fed. Cir. 2010); *Capizzano v. Sec'y of Health & Hum. Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006).[12] Petitioner does not herein assert a Table claim—nor could he, since the only Table claim for brachial neuritis involves tetanus-containing vaccines.

For both Table and Non-Table claims, Vaccine Program petitioners bear a "preponderance of the evidence" burden of proof. Section 13(1)(a). That is, a petitioner must offer evidence that leads the "trier of fact to believe that the existence of a fact is more probable than its nonexistence before [he] may find in favor of the party who has the burden to persuade the judge of the fact's existence." *Moberly*, 592 F.3d at 1322 n.2; *see also Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984) (mere conjecture or speculation is insufficient under a preponderance standard). Proof of medical certainty is not required. *Bunting v. Sec'y of Health & Hum. Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991). In particular, a petitioner must demonstrate that the vaccine was "not only [the] but-for cause of the injury but also a substantial factor in bringing about the injury." *Moberly*, 592 F.3d at 1321 (quoting *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1352–53 (Fed. Cir. 1999)); *Pafford v. Sec'y of Health & Hum. Servs*., 451 F.3d 1352, 1355 (Fed. Cir. 2006). A petitioner may not receive a Vaccine Program award based solely on his assertions; rather, the petition must be supported by either medical records or by the opinion of a competent physician. Section 13(a)(1).

In attempting to establish entitlement to a Vaccine Program award of compensation for a Non-Table claim, a petitioner must satisfy all three of the elements established by the Federal Circuit in *Althen v. Sec'y of Health and Hum. Servs.,* 418 F.3d 1274, 1278 (Fed. Cir. 2005): "(1) a

[12] Decisions of special masters (some of which I reference in this ruling) constitute persuasive but not binding authority. *Hanlon v. Sec'y of Health & Hum. Servs.*, 40 Fed. Cl. 625, 630 (1998). By contrast, Federal Circuit rulings concerning legal issues are binding on special masters. *Guillory v. Sec'y of Health & Hum. Servs.*, 59 Fed. Cl. 121, 124 (2003), *aff'd* 104 F. App'x. 712 (Fed. Cir. 2004); *see also Spooner v. Sec'y of Health & Hum. Servs.*, No. 13-159V, 2014 WL 504728, at *7 n.12 (Fed. Cl. Spec. Mstr. Jan. 16, 2014).

medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury."

Each *Althen* prong requires a different showing. Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received *can cause* the type of injury alleged. *Pafford*, 451 F.3d at 1355–56 (citations omitted). To satisfy this prong, a petitioner's theory must be based on a "sound and reliable medical or scientific explanation." *Knudsen v. Sec'y of Health & Hum. Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Such a theory must only be "legally probable, not medically or scientifically certain." *Id.* at 549.

Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *Andreu v. Sec'y of Health & Hum. Servs.*, 569 F.3d 1367, 1378–79 (Fed. Cir. 2009) (citing *Capizzano*, 440 F.3d at 1325–26). Special masters, despite their expertise, are not empowered by statute to conclusively resolve what are essentially thorny scientific and medical questions, and thus scientific evidence offered to establish *Althen* prong one is viewed "not through the lens of the laboratorian, but instead from the vantage point of the Vaccine Act's preponderant evidence standard." *Id.* at 1380. Accordingly, special masters must take care not to increase the burden placed on petitioners in offering a scientific theory linking vaccine to injury. *Contreras*, 121 Fed. Cl. at 245 ("[p]lausibility . . . in many cases *may* be enough to satisfy *Althen* prong one" (emphasis in original)).

In discussing the evidentiary standard applicable to the first *Althen* prong, the Federal Circuit has consistently rejected the contention that it can be satisfied merely by establishing the proposed causal theory's scientific or medical *plausibility*. *See Boatmon v. Sec'y of Health & Hum. Servs.*, 941 F.3d 1351, 1359 (Fed. Cir. 2019); *LaLonde v. Sec'y of Health & Hum. Servs.*, 746 F.3d 1334, 1339 (Fed. Cir. 2014) ("[h]owever, in the past we have made clear that simply identifying a 'plausible' theory of causation is insufficient for a petitioner to meet her burden of proof." (citing *Moberly*, 592 F.3d at 1322)); *see also Howard v. Sec'y of Health & Hum. Servs*., 2023 WL 4117370, at *4 (Fed. Cl. May 18, 2023) ("[t]he standard has been preponderance for nearly four decades"), *appeal docketed,* No. 23-1816 (Fed. Cir. Apr. 28, 2023). And petitioners always have the ultimate burden of establishing their *overall* Vaccine Act claim with preponderant evidence. *W.C. v. Sec'y of Health & Hum. Servs.*, 704 F.3d 1352, 1356 (Fed. Cir. 2013) (citations omitted); *Tarsell v. United States*, 133 Fed. Cl. 782, 793 (2017) (noting that *Moberly* "addresses the petitioner's overall burden of proving causation-in-fact under the Vaccine Act" by a preponderance standard).

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*,

569 F.3d at 1375–77; *Capizzano*, 440 F.3d at 1326; *Grant v. Sec'y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). In establishing that a vaccine "did cause" injury, the opinions and views of the injured party's treating physicians are entitled to some weight. *Andreu*, 569 F.3d at 1367; *Capizzano*, 440 F.3d at 1326 ("medical records and medical opinion testimony are favored in vaccine cases, as treating physicians are likely to be in the best position to determine whether a 'logical sequence of cause and effect show[s] that the vaccination was the reason for the injury'") (quoting *Althen*, 418 F.3d at 1280). Medical records are generally viewed as particularly trustworthy evidence, since they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Medical records and statements of a treating physician, however, do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. Section 13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Hum. Servs*., 88 Fed. Cl. 706, 746 n.67 (2009) ("there is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted"). As with expert testimony offered to establish a theory of causation, the opinions or diagnoses of treating physicians are only as trustworthy as the reasonableness of their suppositions or bases. The views of treating physicians should be weighed against other, contrary evidence also present in the record—including conflicting opinions among such individuals. *Hibbard v. Sec'y of Health & Hum. Servs.*, 100 Fed. Cl. 742, 749 (2011) (not arbitrary or capricious for special master to weigh competing treating physicians' conclusions against each other), *aff'd*, 698 F.3d 1355 (Fed. Cir. 2012); *Veryzer v. Sec'y of Dept. of Health & Hum. Servs.*, No. 06-522V, 2011 WL 1935813, at *17 (Fed. Cl. Spec. Mstr. Apr. 29, 2011), *mot. for review den'd*, 100 Fed. Cl. 344, 356 (2011), *aff'd without opinion*, 475 F. Appx. 765 (Fed. Cir. 2012).

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1281. That term has been equated to the phrase "medically-acceptable temporal relationship." *Id.* A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation." *de Bazan v. Sec'y of Health & Hum. Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). The explanation for what is a medically acceptable timeframe must align with the theory of how the relevant vaccine can cause an injury (*Althen* prong one's requirement). *Id.* at 1352; *Shapiro v. Sec'y of Health & Hum. Servs.*, 101 Fed. Cl. 532, 542 (2011), *recons. den'd after remand*, 105 Fed. Cl. 353 (2012), *aff'd mem.*, 503 F. Appx. 952 (Fed. Cir. 2013); *Koehn v. Sec'y of Health & Hum. Servs.*, No. 11-355V, 2013 WL 3214877 (Fed. Cl. Spec. Mstr. May 30, 2013), *mot. for rev. den'd* (Fed. Cl. Dec. 3, 2013), *aff'd*, 773 F.3d 1239 (Fed. Cir. 2014).

B. *Legal Standards Governing Factual Determinations*

The process for making determinations in Vaccine Program cases regarding factual issues begins with consideration of the medical records. Section 11(c)(2). The special master is required to consider "all [ ] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." Section 13(b)(1)(A). The special master is then required to weigh the evidence presented, including contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (determining that it is within the special master's discretion to determine whether to afford greater weight to contemporaneous medical records than to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is evidenced by a rational determination).

As noted by the Federal Circuit, "[m]edical records, in general, warrant consideration as trustworthy evidence." *Cucuras*, 993 F.2d at 1528; *Doe/70 v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 598, 608 (2010) ("[g]iven the inconsistencies between petitioner's testimony and his contemporaneous medical records, the special master's decision to rely on petitioner's medical records was rational and consistent with applicable law"), *aff'd*, *Rickett v. Sec'y of Health & Hum. Servs*., 468 F. App'x 952 (Fed. Cir. 2011) (non-precedential opinion). A series of linked propositions explains why such records deserve some weight: (i) sick people visit medical professionals; (ii) sick people attempt to honestly report their health problems to those professionals; and (iii) medical professionals record what they are told or observe when examining their patients in as accurate a manner as possible, so that they are aware of enough relevant facts to make appropriate treatment decisions. *Sanchez v. Sec'y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *2 (Fed. Cl. Spec. Mstr. Apr. 10, 2013); *Cucuras v. Sec'y of Health & Hum. Servs.*, 26 Cl. Ct. 537, 543 (1992), *aff'd*, 993 F.2d at 1525 (Fed. Cir. 1993) ("[i]t strains reason to conclude that petitioners would fail to accurately report the onset of their daughter's symptoms").

Accordingly, if the medical records are clear, consistent, and complete, then they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03–1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). Indeed, contemporaneous medical records are often found to be deserving of greater evidentiary weight than oral testimony—especially where such testimony conflicts with the record evidence. *Cucuras*, 993 F.2d at 1528; *see also Murphy v. Sec'y of Health & Hum. Servs*., 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed. Cir. 1992), *cert. den'd*, *Murphy v. Sullivan*, 506 U.S. 974 (1992) (citing *United States v. United States Gypsum Co.*, 333 U.S. 364, 396 (1947) ("[i]t has generally been held that oral testimony which is in conflict with contemporaneous documents is entitled to little evidentiary

weight.")).

However, the Federal Circuit has also noted that there is no formal "presumption" that records are accurate or superior on their face to other forms of evidence. *Kirby v. Sec'y of Health & Hum. Servs.,* 997 F.3d 1378, 1383 (Fed. Cir. 2021). There are certainly situations in which compelling oral or written testimony (provided in the form of an affidavit or declaration) may be more persuasive than written records, such as where records are deemed to be incomplete or inaccurate. *Campbell v. Sec'y of Health & Hum. Servs*., 69 Fed. Cl. 775, 779 (2006) ("like any norm based upon common sense and experience, this rule should not be treated as an absolute and must yield where the factual predicates for its application are weak or lacking"); *Lowrie*, 2005 WL 6117475, at *19 ("[w]ritten records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent") (quoting *Murphy*, 23 Cl. Ct. at 733)). Ultimately, a determination regarding a witness's credibility is needed when determining the weight that such testimony should be afforded. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

When witness testimony is offered to overcome the presumption of accuracy afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Sanchez*, 2013 WL 1880825, at *3 (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). In determining the accuracy and completeness of medical records, the Court of Federal Claims has listed four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203–04 (2013), *aff'd*, 746 F.3d 1334 (Fed. Cir. 2014). In making a determination regarding whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony at hearing, there must be evidence that this decision was the result of a rational determination. *Burns*, 3 F.3d at 417.

C. *Analysis of Expert Testimony*

Establishing a sound and reliable medical theory often requires a petitioner to present expert testimony in support of his claim. *Lampe v. Sec'y of Health & Hum. Servs*., 219 F.3d 1357, 1361 (Fed. Cir. 2000). Vaccine Program expert testimony is usually evaluated according to the factors for analyzing scientific reliability set forth in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 594–96 (1993). *See Cedillo v. Sec'y of Health & Hum. Servs.*, 617 F.3d 1328, 1339 (Fed. Cir. 2010) (citing *Terran v. Sec'y of Health & Hum. Servs.*, 195 F.3d 1302, 1316 (Fed. Cir. 1999). Under *Daubert*, the factors for analyzing the reliability of testimony are:

> (1) whether a theory or technique can be (and has been) tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether there is a known or potential rate of error and whether there are standards for controlling the error; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Terran, 195 F.3d at 1316 n.2 (citing *Daubert*, 509 U.S. at 592–95).

In the Vaccine Program the *Daubert* factors play a slightly different role than they do when applied in other federal judicial settings, like the district courts. Typically, *Daubert* factors are employed by judges (in the performance of their evidentiary gatekeeper roles) to exclude evidence that is unreliable or could confuse a jury. By contrast, in Vaccine Program cases these factors are used in the *weighing* of the reliability of scientific evidence proffered. *Davis v. Sec'y of Health & Hum. Servs*., 94 Fed. Cl. 53, 66–67 (2010) ("uniquely in this Circuit, the *Daubert* factors have been employed also as an acceptable evidentiary-gauging tool with respect to persuasiveness of expert testimony already admitted"). The flexible use of the *Daubert* factors to evaluate the persuasiveness and reliability of expert testimony has routinely been upheld. *See, e.g.*, *Snyder*, 88 Fed. Cl. at 742–45. In this matter (as in numerous other Vaccine Program cases), *Daubert* has not been employed at the threshold, to determine what evidence should be admitted, but instead to determine whether expert testimony offered is reliable and/or persuasive.

Respondent frequently offers one or more experts in order to rebut a petitioner's case. Where both sides offer expert testimony, a special master's decision may be "based on the credibility of the experts and the relative persuasiveness of their competing theories." *Broekelschen v. Sec'y of Health & Hum. Servs*., 618 F.3d 1339, 1347 (Fed. Cir. 2010) (citing *Lampe*, 219 F.3d at 1362). However, nothing requires the acceptance of an expert's conclusion "connected to existing data only by the *ipse dixit* of the expert," especially if "there is simply too great an analytical gap between the data and the opinion proffered." *Snyder*, 88 Fed. Cl. at 743 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 146 (1997)); *see also Isaac v. Sec'y of Health & Hum. Servs*., No. 08–601V, 2012 WL 3609993, at *17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for review den'd*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. App'x. 999 (Fed. Cir. 2013) (citing *Cedillo*, 617 F.3d at 1339). Weighing the relative persuasiveness of competing expert testimony, based on a particular expert's credibility, is part of the overall reliability analysis to which special masters must subject expert testimony in Vaccine Program cases. *Moberly*, 592 F.3d at 1325–26 ("[a]ssessments as to the reliability of expert testimony often turn on credibility determinations"); *see also Porter v. Sec'y of Health & Hum. Servs*., 663 F.3d 1242, 1250 (Fed. Cir. 2011) ("this court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act").

D. *Consideration of Medical Literature*

Both parties filed medical and scientific literature in this case, but not all such items factor into the outcome of this decision. While I have reviewed all the medical literature submitted, I discuss only those articles that are most relevant to my determination and/or are central to Petitioner's case—just as I have not exhaustively discussed every individual medical record filed. *Moriarty v. Sec'y of Health & Hum. Servs.*, No. 2015–5072, 2016 WL 1358616, at *5 (Fed. Cir. Apr. 6, 2016) ("[w]e generally presume that a special master considered the relevant record evidence even though he does not explicitly reference such evidence in his decision") (citation omitted); *see also Paterek v. Sec'y of Health & Hum. Servs.,* 527 F. App'x 875, 884 (Fed. Cir. 2013) ("[f]inding certain information not relevant does not lead to—and likely undermines—the conclusion that it was not considered").

ANALYSIS

I. Treatment of Brachial Neuritis Claims

Although the Vaccine Injury Table only provides for a claim of brachial neuritis after receipt of the tetanus vaccine, special masters have on many occasions found that *other* vaccines—including the flu vaccine—might also be causal of the condition. *Morgan v. Sec'y of Health & Hum. Servs.*, No. 16-269V, 2023 WL 3984415 (Fed. Cl. Spec. Mstr. June 12. 2023) (finding two to three days post-intradermal influenza vaccination and the progression of pain and weakness over several days to be an acceptable temporal association); *Abels v. Sec'y of Health & Hum. Servs.*, No. 18-558V, 2022 WL 2036101 (Fed. Cl. Spec. Mstr. May 6, 2022) (flu vaccine deemed causal of brachial neuritis).

When adjudicating comparable claims, my decisions have turned less on whether the vaccine at issue *could* cause brachial neuritis, and more on whether onset occurred in a medically acceptable timeframe. *See, e.g.*, *Greene v. Sec'y of Health & Hum. Servs.*, No. 11-631V, 2019 WL 4072110 (Fed. Cl. Spec. Mstr. Aug. 2, 2019) (41-day onset after tetanus vaccine too long to be causal in Table claim), *mot. for rev. den'd*, 146 Fed. Cl. 655 (Fed. Cl. 2020), *aff'd*, 841 Fed. App'x. 195 (Fed. Cir. 2020); *Garner v. Sec'y of Health & Human Servs.*, No. 15-063V, 2017 WL 1713184 (Fed. Cl. Mar. 24, 2017), *mot. for rev. den'd*, 2017 WL 3483352 (Fed. Cl. July 31, 2017) (dismissing claim that the Hepatitis A and B vaccines caused brachial neuritis, where claimant reported arm or shoulder pain 45 days post-vaccination).

II. Petitioner has Not Preponderantly Established Brachial Neuritis as His Injury

Here, as in many cases, disposition of the claim turns on its proper, evidence-supported characterization. *Broekelschen*, 618 F.3d at1350. Petitioner solely seeks to establish brachial

neuritis as his injury, and thus disposition of the case depends on the finding that this injury has preponderant evidentiary support. Unfortunately, the record does not support that conclusion.[13]

Dr. Callaghan made a number of reasonable and persuasive points suggesting a brachial neuritis diagnosis was not reflected by the medical record. First, he correctly observed that the proposed diagnosis was not corroborated by record evidence of *contemporaneous treater support*. In fact, arguably the best treater diagnostic opinion for the alleged brachial neuritis injury comes from Dr. McQueen's exams of Petitioner—which occurred in September 2019 and then March 2020, and thus significantly after the vaccination and onset. And even the findings from those visits are more supportive of the diagnoses embraced by Dr. Callaghan.

Second, Respondent successfully demonstrated that the criteria for brachial neuritis are not ultimately met given the facts of Petitioner's medical history. Dr. Callaghan referred to the Table criteria in advancing this aspect of his opinion (*see* Callaghan First Rep. at 5), and although those elements are not controlling for this non-Table claim, they provide useful guidance for brachial neuritis's elements. The criteria establishing a Table claim for brachial neuritis include:

(i) Pain in the affected arm and shoulder is a presenting symptom and occurs within the specified time-frame;
(ii) Weakness;
   a. Clinical diagnosis in the absence of nerve conduction and electromyographic studies requires weakness in muscles supplied by more than one peripheral nerve.
   b. Nerve conductions studies (NCS) and electromyographic (EMG) studies localizing the injury to the brachial plexus are required before the

[13] Because the alleged injury lacks preponderant support, I need not conduct an *Althen* analysis. *Lombardi v. Sec'y of Health & Hum. Servs.*, 656 F.3d 1343, 1353 (Fed. Cir. 2011). I note, however, that I would not have trouble finding on this record that the flu vaccine "can cause" brachial neuritis. Despite the reasonable objections made to the theory by Dr. MacGinnitie, the evidence offered was sufficiently preponderant on the question of vaccine causality for an *Althen* prong one finding in Petitioner's favor. The timeframe prong under *Althen* presents a more difficult question, since onset occurred fairly close in time to vaccination, and thus is not consistent with an adaptive immune-mediated response. However, the immune memory arguments posited by Dr. Andersson have some persuasive value in the context of a brachial neuritis injury. In addition, although Respondent did effectively note the strong possibility that Petitioner's surgery was a "factor unrelated" explanation for brachial neuritis (and I did not find persuasive Petitioner's argument that surgery is only a risk due to positional effects—rather, surgery clearly could trigger an immune response as well), Respondent did not *exclude* the possibility of the vaccine as a substantial factor. *Stone v. Sec'y of Health & Hum. Servs.*, 95 Fed. Cl. 233, 237 n.5 (2010).

Of course, not establishing the alleged injury in this case is equivalent to failing to prove that the flu vaccine "did cause" it (meaning the second *Althen* prong is not established). The evidence—both from the record and based on expert submissions—heavily preponderates against the finding that Petitioner's injury is best characterized as brachial neuritis.

diagnosis can be made if weakness is limited to muscles supplied by a single peripheral nerve.

(iii) Motor, sensory, and reflex findings on physical examination and the results of NCS and EMG studies, if performed, must be consistent in confirming that dysfunction is attributable to the brachial plexus; and

(iv) No other condition or abnormality is present that would explain the vaccine recipient's symptoms.

42 C.F.R.§ 100.3(a), (c)(6).

As Dr. Callaghan noted, Petitioner never exhibited symptoms or examination findings indicating *weakness* in the left arm compared to the right arm despite two visits to his neurologists and several to his PCP. Callaghan First Rep. at 5; Tr. at 206–209; 220–21. Weakness is a central feature of brachial neuritis, yet evidence of it is absent in this medical record. *See, e.g.*, Tsairis at 111.

The record also lacked evidence of "motor, sensory, reflexes findings, and EMG/NCS studies confirming dysfunction in the brachial plexus." Callaghan First Rep. at 5. Rather, EMG and NCS testing were supportive of CTS and radiculopathy. *Id.* These conditions were all explanatory for Petitioner's complaints. *Id.* at 7; Callaghan Second Rep. at 2 ("Petitioner's symptoms of left shoulder pain and numbness, tingling, and burning in the 1-3 digits of the left hand are exactly the type of symptoms one would expect from a left C5 radiculopathy as demonstrated on the EMG/NCS"). That diagnostic testing was not supportive of brachial neuritis, as the contemporaneous record established. *See* Ex. 8 at 14-16 (EMG confirming bilateral CTS and chronic cervical radiculopathy).

Finally, the characterization of Petitioner's injury as an especially uncommon, pure sensory form of brachial neuritis was effectively rebutted by Dr. Callaghan as lacking record evidence substantiation. Callaghan Second Rep. at 1. No treater so diagnosed Petitioner. In addition, the EMG/NCS testing did not reveal injury to sensory nerves (as would be expected in a pure sensory form of brachial neuritis), but instead was (again) fully consistent with CTS, cervical radiculopathy, and neuropathy (all of which were the diagnoses made by Petitioner's treating physicians).

Dr. Andersson was a qualified and competent expert, fully capable of offering an opinion on the neurologic issues in dispute, and he made many credible points in Petitioner's favor. The case was certainly reasonably disputed. But his contentions about the appropriateness of a brachial neuritis diagnosis were ultimately lacking in sufficient record support.

CONCLUSION

Petitioner has not established the alleged brachial neuritis injury with sufficient preponderant evidence, and therefore is not entitled to an award of compensation. In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court **SHALL ENTER JUDGMENT** in accordance with the terms of this Decision.[14]

IT IS SO ORDERED.

/s/ Brian H. Corcoran
Brian H. Corcoran
Chief Special Master

[14] Pursuant to Vaccine Rule 11(a), the parties may expedite entry of judgment if (jointly or separately) they file notices renouncing their right to seek review.